



<b>July 8, 2004</b>	2:00 pm EDT
<b>Attendees:</b>	<p><i>Attendees:</i></p> <p>City of Hope: Joyce Niland  Oregon Health and Science University: Ed Quick; Vincent Yau  University of Iowa: Terry Braun  Washington University—Siteman: Mark Watson  Fox Chase: Pat Harsche-Weeks  Patient Advocate: Don Cecchi  NCI - Wendy Patterson; Leslie Derr; Brenda Duggan  BAH - Phan Winter</p>
<b>Introduction</b>	<p>Wendy Patterson opened the meeting, reviewed the agenda, and asked whether the group had comments on the notes from the 6/24/04 teleconference. Response to the notes was positive though a few corrections were offered and changes incorporated.</p>
<b>Report from Liaisons</b>	<p><u>Training</u> (Ed Quick -OHSU): The entire Training WG has not met since the DSIC WG's last call. The Developer SIG is working on a white paper and outline of training materials needed by the caBIG community.</p> <p><u>Strategic Planning</u>: Michael Becich (University of Pittsburgh) was absent.</p> <p><u>Integrative Cancer Research (ICR)</u> (Terry Braun - University of Iowa – Holden): The entire IC Workspace has not met since the DSIC WG's last call. Juli Klemm, the workspace facilitator (BAH) is planning a face-to- face meeting to talk about projects in progress. The Gene Annotation SIG's last teleconference was July 1. The group received presentations on the SEED and GBrowse tools. The Pathway and Microarray SIGs also received tools presentations during teleconferences held July 6 and 7, respectively, but Terry did not attend those meetings.</p> <p><u>Clinical Trials</u>: Don Connelly (University of Minnesota) was absent.</p> <p><u>Tissue Banks and Pathology Tools (TBPT)</u> (Mark Watson - Washington University - Siteman): At its last meeting, the TBPT Workspace discussed plans for a face-to-face meeting in</p>



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	<p>September. This group has not yet identified issues for the DSIC WG to address. Rather, most discussions have evolved around the group's CDE and Vocabulary needs.</p>
<p><b>Update on Survey Development</b></p>	<p>Mark Watson presented additional survey questions to the group. However, he wondered whether the survey will retrieve the desired data and asked the group to reconsider its goal in preparing the survey. He asked whether a better approach would be to adopt the suggestion from the last teleconference of drafting a "rule book," which would summarize what caBIG expects from participants in terms of data sharing, and ask for feedback from caBIG Centers.</p> <p>Don Cecchi, who has developed a number of questionnaires, preferred Mark's new questions because the old set was too general. He thought that asking people who would be affected by the survey to review the survey instrument would result in early buy-in. He asked whether the DSIC WG has solicited feedback from the caBIG IP community. Wendy responded that the group has asked for IP contacts but has not yet requested their input. She noted that Pat Harsche-Weeks, who manages tech transfer matters at Fox Chase, has articulated the IP community's concerns thus far. Don reiterated the importance of getting the actual respondents to participate early on to provide assurance that they have a stake in the process.</p> <p>Wendy agreed with Mark that the goal is to prepare a document that communicates caBIG expectations, but was uncomfortable with calling it a "rule book," which connotes a "top-down" approach. She thought it would be more reasonable to pursue the idea of principles that Centers should keep in mind when negotiating agreements. Wendy suggested that the group draft a statement that addresses the rationale for each "rule". This draft should then be sent to each Center's IP contact for review and feedback on potential problems.</p> <p>Joyce suggested a combination approach of first circulating a scenario-based survey and following up with the proposed "guidebook." In both cases, these efforts should be piloted at DSIC WG centers.</p> <p>Pat expressed concern that some centers may not be aware that some data to be shared in caBIG activities is already subject to third party rights. For example, pursuant to an agreement with a pharmaceutical company, an institution generates data on specific markers from patient studies that it may use internally for research but not for other purposes.</p>



Consequently, survey respondents need to be made aware that some of data and/or material made available for caBIG activities will be subject to restrictions on use due to preexisting agreements. She commented that the survey should aim to assess how free a center is to share data for use in caBIG activities. She hoped that the survey would be viewed as an educational effort that encourages centers to accept fewer restrictions so they can share data in caBIG activities.

Ed brought up the connection between the survey and the discussion on hierarchy of data access. He had the impression that responses to the survey questions would be used to delineate the hierarchy. Ed thought the goal was to outline the data access hierarchy, i.e., to define levels of access within a framework of sharing with the larger community.

Mark pointed out that Centers may not be able to renegotiate preexisting agreements but that the DSIC WG can develop a model agreement to be used as guidance in negotiating future agreements. The model agreement could provide a tangible set of considerations for moving forward in sharing data in caBIG activities.

Wendy asked about practical next steps. Joyce Niland suggested drafting a model agreement and using it with the survey in a combined approach. Pat thought that the group should drop the idea of a questionnaire and instead draft a document listing "points for consideration" with an appropriate preface about caBIG.

Don thought that the group should explain the benefits of data sharing to survey respondents. Pat didn't think this would be a hard sell. She said she knew most IP directors at the Centers and thought that the response will be generally positive. Don asked next about the reaction of the pharmaceutical industry, whose practice tends to be to give away as little information as possible. Pat responded that the recent movement toward public domain genome databases has increased the perceived value of sharing relative to commercial rights protection.

Wendy stated that caBIG should emphasize that Centers will reap benefits from sharing data and that DSIC WG "points for consideration" would support individual institutions in negotiating these issues with the pharmaceutical industry. Don suggested that all documents developed by the DSIC WG articulate the benefits of sharing data to stake holders.

Vincent added his perspective from the software open source model. He recently downloaded an NIH tool and only needed a



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few days to learn how to use and adapt the tool rather than weeks or months if it had been necessary to develop the tool from scratch. In his view, applying this model to drug and biomarker development could significantly speed up the discovery process.

Pat commented that not everyone would adhere to a research model that promotes open data access. However, she thought that most in the academic community would probably go along readily and that even industry would see value in sharing. Wendy stated that conducting an open conversation is a good idea and that the questionnaire would be a good way to open the conversation.

Don wondered about using the word “agreement” in a document setting out data sharing principles. He was concerned that it might raise multiple issues when encountered by company lawyers. After some discussion, the group concluded that it supported the use of “agreement” to invite more serious attention from industry.

Wendy concluded the discussion by stating that a combination of approaches could be used. The group can send the survey out to caBIG’s IP/tech transfer community to assess existing difficulties in sharing data and then use the responses to inform the development of a model for data sharing within caBIG. She asked what the group thought should happen next and what changes, if any, were required for the survey. Pat volunteered to talk to a few of her IP colleagues and draft a model agreement. The group generally agreed that the next step forward is to incorporate Mark’s new questions and Joyce’s scenario section into the survey. Phan will then send out a package to the DSIC WG IP contacts for their feedback.

**Implementation of a  
National Clinical Trials  
Registry by caBIG**

Wendy opened conversation on the implementation of a National Clinical Trials Registry.

Ed asked whether this initiative relates to the AACI, but no one in the group was familiar with AACI. He then asked whether there are any barriers to the implementation of such a registry. He pointed out that most Centers already have procedures to register data and that any national registry should look at what has already been done.

Wendy pointed out that companies may not be interested in participating in view of concerns about protecting proprietary information. Others in the group mentioned that the general



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	<p>principle is the protection of confidential treatment while reserving the rights of investigators to publish, which is embedded in most cancer center clinical trial agreements.</p> <p>Ed wondered about the purpose of a national registry. Pat responded that it is intended to provide access to trial outcomes and is based on complaints that negative trials are not published. However, she pointed out that all trials conducted at her Center are published so this is a non-issue for her Center.</p>			
<p><b>Open Source Model to Drug Development and Data Access</b></p>	<p>This agenda item was not covered due to time constraints.</p>			
<p><b>Items for Next Teleconference: June 24th</b></p>	<p>There were no objections to skipping the teleconference scheduled for July 22; the group agreed that the next meeting will occur on August 5.</p>			
<p><b>Action Items:</b></p>	<p><b>Name Responsible</b></p>	<p><b>Action Item</b></p>	<p><b>Date Due</b></p>	<p><b>Notes</b></p>
	<p>Joyce Niland</p>	<p>Scenario section for survey</p>	<p>7/13/2004</p>	
	<p>Pat Harshe-Weeks</p>	<p>Develop model agreement</p>	<p>7/30/2004</p>	<p>Pat will begin discussion with a few colleagues and will report back to DSIC</p>
	<p>Phan</p>	<p>Send out survey to IP contacts</p>	<p>7/15/2004</p>	